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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/642,504	08/18/2000	J. Bruce Pitner	P-2776P1P1P1	7467

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[REDACTED] EXAMINER

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ART UNIT	PAPER NUMBER
1627	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 09/642,504	Applicant(s) Pitner et al.
Examiner Ralph Gitomer	Art Unit 1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on Feb 7, 2002.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-90 is/are pending in the application.
- 4a) Of the above, claim(s) 17-48 and 63-90 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-16 and 49-62 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) Notice of References Cited (PTO-892) 18) Interview Summary (PTO-413) Paper No(s). _____
- 16) Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) Notice of Informal Patent Application (PTO-152)
- 17) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) Other: _____

Applicant's election with traverse of Group I, claims 1-16, 49-62, in Paper No. 6 is acknowledged. The traversal is on the ground(s) that the groups share common subject matter, a restriction is discretionary. This is not found persuasive because in virtually all restriction situations, there is some common subject matter and as this may be discretionary, the decision was made to restrict.

The requirement is still deemed proper and is therefore made 10 FINAL.

Please inform the examiner as to how this application differs from each of the parent applications so the proper priority date may be granted. And please update the status of the related applications in the specification. The related 15 applications are not available to the examiner at this time so any double patenting and other issues will be considered in the future.

A reading of the claims and specification do not reveal a specific functional problem solution or any particular point of 20 novelty. Therefore, what has been searched and considered here, is immobilizing the conventional luminescent indicator.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under 25 this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1-4, 6, 7, 13, 49-52, 54, 55, 59 are rejected under 35 U.S.C. 102(b) as being anticipated by Bacon.

Bacon (Anal Chem) entitled ~~Determination of Oxygen~~

Concentrations by Luminescence Quenching of a Polymer Immobilized

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Transition Metal Complex~~s~~ teaches in the abstract, tris(4,7-diphenyl-1, 10-phenanthroline)ruthenium(II) immobilized in a silicone rubber for measuring oxygen concentrations. On page 2780 column 2, silica gel bound luminescent dye is separated from the solution being measured. On page 2781 column 2, a number of other polymers were tried and their qualities discussed.

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Claims 1-4, 10, 13, 49-52, 58, 59 are rejected under 35 U.S.C. 102(b) as being anticipated by Parker.

Parker (Fiber Optic Sensors) entitled ~~Chemical Sensors~~

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Based on Oxygen Detection by Optical Methods~~s~~ teaches in the abstract, fluorescence quenching to measure oxygen concentration with 9,10-diphenyl anthracene. On page 156, even when immobilized, fluorescent molecules show a reduction in fluorescence intensity with increasing oxygen concentration.

25

Thus, solid materials can be developed to measure the concentration of oxygen. Chemical reactions that either consume or produce oxygen can be determined. The fluorescence compound

may be physically immobilized in a polymer such as silicone. On page 157 the reactions take place in cuvettes.

All the features of the claims are taught by the above references for the same functions as claimed.

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

10 (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15 This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a),
20 the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103[©] and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 5, 8, 9, 11, 12, 14-16, 53, 56, 57, 60-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over each of Bacon and Parker.

Bacon (Anal Chem) entitled ~~Determination of Oxygen Concentrations by Luminescence Quenching of a Polymer Immobilized Transition Metal Complex~~ teaches in the abstract, tris(4,7-diphenyl-1, 10-phenanthroline)ruthenium(II) immobilized in a silicone rubber for measuring oxygen concentrations. On page 2780 column 2, silica gel bound luminescent dye is separated from the solution being measured. On page 2781 column 2, a number of polymers were tried and their qualities discussed.

Parker (Fiber Optic Sensors) entitled ~~Chemical Sensors Based on Oxygen Detection by Optical Methods~~ teaches in the abstract, fluorescence quenching to measure oxygen concentration with 9,10-diphenyl anthracene. On page 156, even when immobilized, fluorescent molecules show a reduction in fluorescence intensity with increasing oxygen concentration. Thus, solid materials can be developed to measure the concentration of oxygen. Chemical reactions that either consume or produce oxygen can be determined. The fluorescence compound may be physically immobilized in a polymer such as silicone. On page 157 the reactions take place in cuvettes.

Claims 5, 53 differ from the above references in that they specify the compound is adsorbed on solid silica particles.

Claims 8, 9, 56, 57 differ from the above references in that they

are directed to other ruthenium salts. Claims 11 and 12 differ from the above references in that they are directed to the solutions are open or closed. Claims 14-16, 60-62 differ from the above references in that they are directed to the enzymes are 5 in specific cells and may include P450 enzymes particularly.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to immobilize the luminescent compound on silica particles because silica particles 10 are well known in this art for immobilizing desired compounds. The references teach common ruthenium compounds and the presently claimed compounds are known in this art for their claimed function. The solutions of the references are either open or closed and both are shown in the references cited herein for 15 measuring oxygen concentrations. No novelty is seen in the analyte being any particular type of cell or known redox enzyme system where the method of measuring is known for the same function as claimed and would have the expected results.

20 Claims 1-16, 49-62 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the following applies in all occurrences.

In claim 1 line 1, ~~the presence~~ lacks antecedent basis.
In claim 1(i) ~~the enzyme(s)~~ lacks antecedent basis. The are many other instances of lack of antecedent basis to numerous to enumerate here. In claim 1(iv) ~~capable of~~ is indefinite regarding what actually occurs. In claim 1(v) what increase is not understood in context. The preamble of claim 1 is directed to determining reactions but step (v) is directed to determining an enzyme. Claim 13 is entirely indefinite where what the biomaterials may be is not seen and what they may be effective for is not set forth.

The title of the invention is not aptly descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

15 The following prior art pertinent to applicant's disclosure is made of record and not relied upon:

Stitt (5,567,598) is a related case with a different inventive entity.

20 Walt (5,250,264) teaches immobilized ruthenium dyes.

Cox (5,034,189) teaches immobilized indicators.

Gentle (5,998,517) teaches the presently claimed compounds.

Berndt (6,080,574) teaches the presently claimed ruthenium compounds for detecting microorganisms.

25 Morris (WO 92/12413) teaches determining bacterial CO₂.

Fraatz (EP 0 448 923) teaches sealed gas sensors.

Biology Instruments (SU 1602869) teaches luminescent compounds for determining respiratory activity of microorganisms.

Sasso (Anal Biochem) entitled ~~Ruthenium (II) Tris(bipyridyl) Ion~~

5 as a Luminescent Probe for Oxygen Uptake ~~teaches~~ in the abstract, measuring the rate of oxygen uptake by chemical and enzymatic systems by monitoring the well known quenching effect of oxygen on the light emission of Ru(bpy)ion. On page 240 column 1 measurements of oxygen consumption were performed in

10 cuvettes.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (703) 308-0732. The examiner
15 can normally be reached on Tuesday-Friday from 8:00 am - 5:00 pm. The examiner can also be reached on alternate Mondays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat can be reached on (703) 308-2439. The fax phone number for this Art Unit is (703) 308-
20 4556. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1234. For 24 hour access to patent application information 7 days per week, or for filing

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applications electronically, please visit our website at
www.uspto.gov and click on the button  Patent Electronic Business Center  for more information.

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R Gitomer

Ralph Gitomer
Primary Examiner
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